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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,481	07/09/2001	Stephen Mayo	A-70586-1/RFT/RMS/RMK	5918

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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 01/28/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/902,481

Applicant(s)

MAYO ET AL.

Examiner

Maher M. Haddad

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/12/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

I. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-7, 14 and 29-30, drawn to a structurally biased integrin I domain, wherein the alterations to the protein occur in at least two noncontiguous regions and pharmaceutical composition; classified in Class 530, subclasses 395.
- II. Claims 8-13, drawn to a recombinant nucleic acid encoding the non-naturally occurring integrin I domain, wherein the alterations to the protein occur in at least two noncontiguous regions, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- III. Claims 15-16, drawn to a method for screening for modulators that bind to the open or close conformation of the integrin protein comprising combining a candidate agent with an integrin that is artificially biased to exist in structurally biased conformation and determine binding; classified in Class 453, subclass 7.1.
- IV. Claims 17-20, drawn to a method for making an antibody which binds to the structurally biased integrin I domain, classified in Class 435, subclass 69.1.
- V. Claim 21, drawn to a method executed by a computer under the control of a program comprising receiving and integrin protein backbone structure with variable residue positions, classified in Class 700, subclass 96.
- VI. Claims 22-23, drawn to a method for treating an integrin I domain responsive condition, wherein the condition is an autoimmune disease, comprising administering an integrin I domain protein, classified in Class 514, subclass 2.
- VII. Claims 22 and 24, drawn to a method for treating an integrin I domain responsive condition, wherein the condition is an inflammatory disease, comprising administering an integrin I domain protein, classified in Class 514, subclass 2.
- VIII. Claims 22 and 25, drawn to a method for treating an integrin I domain responsive condition, wherein the condition is a transplant rejection, comprising administering an integrin I domain protein, classified in Class 514, subclass 2.
- IX. Claims 22 and 26, drawn to a method for treating an integrin I domain responsive condition, wherein the condition is an ischemia/reperfusion, comprising administering an integrin I domain protein, classified in Class 514, subclass 2.

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- X. Claims 22 and 27, drawn to a method for treating an integrin I domain responsive condition, wherein the condition is a viral infection, comprising administering an integrin I domain protein, classified in Class 514, subclass 2.
- XI. Claims 22 and 28, drawn to a method for treating an integrin I domain responsive condition, wherein the condition is a cancer, comprising administering an integrin I domain protein, classified in Class 514, subclass 2.

2. Groups I and II are different products. Nucleic acids and polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups III-XI are different methods. A method of screening, a method of making, a method executed by a computer and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups I and V-XI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the structurally biased integrin I domain protein of Group I can be used for affinity purification, in addition to the methods of treating and making recited.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

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Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

- A. If anyone of Groups I-IV and VI-XI is elected, applicant is required to elect a single specific substitution combination (such as the one in SEQ ID NO:3-6). These substitutions are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.
- B. If Group IX is elected, applicant is further required to elect a method for treating an integrin I domain responsive condition, wherein the condition is an ischemia/reperfusion is a) Hypovolemic shock, b) Myocardial infarct or c) cerebral shock. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
January 27, 2003


CHRISTINA CHAN
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